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K070846

510K Summary of Safety & Effectiveness

MiniSling™- Adjustable Polymer Sling & Surgical Mesh with Self-Anchoring System

Company:

Prosurg, Inc
2193 trade Zone blvd
San Jose CA 95131

Contact:

Ashvin Desai ,
Mgr Regulatory Affairs
Tel: (408) 945 -4044

Date Preparaed: June 26, 2007

Device Name: MiniSling™- Adjustable Polymer Sling & Surgical Mesh with Self-Anchoring System

Predicated Devices: BioSling – Bioabsorbable Sling & Surgical Mesh (Ref: K 010533)
Zippere – bioabsorbable / Non-Absorbable Polymer Sling & Mesh (Ref: K 030631)
AMS-Smart Sling System & pelvic Floor Repair System (Ref K 063713)
Gynecare - TVT Secure System & Pelvic Floor Repair System (K 052401)

Device Description:

The MiniSling™- Adjustable Polymer Sling & Surgical Mesh with Modular Anchor System is available with Single use, universal introducer device with notched tip design, compatible with Fixed, Adjustable and Snap-On modular self anchoring fixation ends of urethral sling and surgical mesh. The Introducer tip can be attached to slot in the fixation anchor for quick connect & disconnect for easy delivery of urethral sling and surgical mesh into target soft tissue. The position of Fixation anchors and sling can also be adjusted intra-operatively using introducer. The T anchors and Split anchors can be delivered in to soft tissue using, modified needle device with ease and minimum discomfort to the patient. The introducer device is available in straight, curved malleable and detachable configuration in various length and curvature to meet physician's preference, patient's anatomy & surgical procedure requirements.

Indications for Use:

MiniSling™- Adjustable Polymer Sling & Surgical Mesh with Self-Anchoring System is an implant device that is intended for the treatment of Stress Urinary Incontinence (SUI) resulting from urethral hypermobility or ISD and for implantation to reinforce soft tissue where weakness exists in the Urological, Gynecological, Uro-Gynecological or Gastroentrological anatomy. This includes but not limited to the following procedures: Pub urethral support, and Bladder support, Urethral and Vaginal Prolapse Repair, Colon and Rectal Prolapse Repair, Reconstruction of Pelvic floor and Sacral Colposuspension.

Comparison of technological Characteristics:

The Mini-Sling - Adjustable Polymer Sling & Surgical Mesh with Self-anchoring System is a modification of the currently marketed BioSling and Zippere Urethral Sling and Surgical Mesh used for pelvic floor support. While it represents s a refinement to the predicate systems, the overall technology and the intended use of the both system are identical. Both predicate and proposed systems are designed for treatment of female Strees Urinary Incontinence (SUI) disorders and pelvic floor repair and reconstruction surgery. The materials, manufacturing methods, packaging and sterilization process used are also identical.

Performance Data:

Preclinical testing was performed to ensure that the Urethral Slings and Surgical mesh products performs as intended when used according to the instructions for use. Laboratory product testing has indicated that the urethral Sling and Surgical mesh devices has demonstrated satisfactory performance for its intended applications. Mechanical testing of the devices also demonstrated that the tensile strength and breakage force are equal or more than the predicated devices and are satisfactory for its intended use. The average pull force of tissue fixation anchor is more than 4000 Gms, during initial implantation stage.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Prosurg, Inc
% Mr. Ashvin Desai
Manager, Regulatory Affairs
2193 Trade Zone Boulevard
San Jose, California 95131

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Re: K070846
Trade/Device Name: MiniSling™ Adjustable Polymer Sling & Surgical Mesh with Self Anchoring System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: May 31, 2007
Received: June 05, 2007

Dear Mr. Desai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K070846**

Device Name: **MiniSling™- Adjustable Polymer Sling & Surgical Mesh with Self-Anchoring** System

Indications for Use:

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Prescription Use __X_____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070846